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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,094	10/13/2006	Dietmar Krautwurst	102790-211 (D30126 US)	4405
27380 7590 03/25/2009 NORRIS, MCLAUGHLIN & MARCUS 875 THIRD AVE 18TH FLOOR NEW YORK, NY 10022				
EXAMINER				
WEGERT, SANDRA L				
ART UNIT		PAPER NUMBER		
1647				
MAIL DATE		DELIVERY MODE		
03/25/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/577,094

**Applicant(s)**

KRAUTWURST ET AL.

**Examiner**

SANDRA WEGERT

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restriction***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-3, 5, 7 and 9-11, drawn to a recombinant animal host cell system, comprising a recombinant G-protein coupled receptor and a recombinant CNGA2 channel.

Group II, claim 1, 3-5, 7 and 9-11, drawn to a recombinant animal host cell system, comprising a recombinant G-protein coupled receptor, a recombinant CNGA2 channel, and further comprising a cyclase harmonized to a G-protein coupled receptor.

Group III, claim 1, 3, 5-7 and 9-11, drawn to a recombinant animal host cell system, comprising a recombinant G-protein coupled receptor, a recombinant CNGA2 channel and further comprising a G-protein that is harmonized with the G protein-coupled receptor.

Group IV, claim 1, 3, 5, 7-11 drawn to a recombinant animal host cell system, comprising a recombinant G-protein coupled receptor, a recombinant CNGA2 channel and a potential recombinant specific G-protein coupled receptor.

Group V, claims 12-16, drawn to a method of producing a recombinant animal host cell system.

Group VI, claims 17-20 and 23; drawn to a method for identifying receptor-activating substances, by measuring changes in  $\text{Ca}^{2+}$  influx into the recombinant cellular system.

Group VII, Claims 21, drawn to a method for producing a pharmaceutical composition by measuring changes in  $\text{Ca}^{2+}$  influx into the recombinant cellular system and then formulating the pharmaceutical composition from the receptor-inducing substance.

Group VIII, claims 22, drawn to a method for identifying G-protein coupled receptors, by measuring changes in  $\text{Ca}^{2+}$  influx into the recombinant cellular system.

The inventions listed as Groups do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The first claimed invention lacks a special technical feature because it fails to distinguish the claimed invention from the prior art (Illing, et al, 2002, Mol. Cell. Neurosci., 20: 225-243, of record). The prior art discloses a recombinant cell system comprising an olfactory cell in which recombinant components include: CNGA2,  $G_{\text{olf}}$ , and receptors OR27-3 and OR6-13. This recombinant cell meets all the limitations of the recombinant cell specified in claim 1. Therefore, none of the other claimed inventions can share a special technical feature with the first claimed invention.

In addition, the receptors, cells, and enzymatic proteins comprising or used in Groups I-VIII are all structurally and functionally different chemical compounds, each of which can be made and used without the other compounds. Likewise, the methods of making the cell systems, detecting the ligands and formulating pharmaceutical compositions each require administration or use of different compounds which are structurally and functionally different from each other

and each of which can be made and used without the other. Lack of unity is shown because these compounds and methods lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

In addition, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- 1) type A guanylyl-cyclases,
- 2) type G guanylyl-cyclases,
- 3) pheromone receptors,
- 4) hormone receptors,
- 5) olfactory receptors.

In addition, this application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- 1) HeLa-Cx43/CNGA2/Olf49,
- 2) HeLa-Cx43/CNGA2/G-alpha-olf,
- 3) HeLa-Cx43/CNGA2/G-alpha-olf/Olf49,
- 4) HeLa-Cx43/CNGA2/G-alpha-olf/Olf41,

- 5) HeLa-Cx43/CNGA2/G-alpha-olf/OlfR 6,
- 6) HeLa-Cx43/CNGA2/G-alpha-olf/OR1A1.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Each G-protein-coupled receptor is a unique structure with unique properties including separate functions within a cell and within the organism. Each cell type is a unique recombinant cell-based system with unique properties. Furthermore, each cell represents a separate contribution to the art, with expression in one cell type failing to anticipate or render obvious expression in any other cell type. Furthermore, each receptor and each cell type requires its own search, and has its own phenotypes and uses.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

#### **Advisory information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

SLW  
20 March 2008

/Dong Jiang/  
Primary Examiner, Art Unit 1646